

FDA Science Board Advisory Committee Meeting

November 4, 2005

Public Comments

Presented by Susan Prolman, Esq.
on behalf of the
Union of Concerned Scientists
and
Keep Antibiotics Working

Good afternoon. My name is Susan Prolman and I am here today to present comments on behalf of both the Union of Concerned Scientists and the Keep Antibiotics Working coalition. The Union of Concerned Scientists's Food and Environment Program is dedicated to phasing out the routine, nontherapeutic use of medically important antibiotics in livestock and poultry. Keep Antibiotics Working, a coalition of health, environmental, consumer, humane, and other advocacy groups with a combined nine million members, was formed to address the loss of antibiotic effectiveness as a result of this overuse.

My comments concern the FDA Science Board Advisory Committee's review of the National Antimicrobial Resistance Monitoring System (NARMS).

First, the Union of Concerned Scientists and Keep Antibiotics Working strongly support NARMS.

Antimicrobial resistance is a growing threat to the public health. NARMS is the primary tool within the United States government for monitoring changes in antimicrobial resistance in foodborne pathogens. Comprehensive, ongoing assessment of the resistance of foodborne pathogens to antimicrobial drugs is essential to the protection of the public health and the management of the increasing risks of resistant disease, including identifying emerging problems. Data from NARMS are used to determine the effectiveness of antimicrobial resistance mitigation programs carried out between the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and Centers for Disease Control and Prevention (CDC). In addition, the data are vital in disease outbreak investigations and can be used to help create treatment guidelines for foodborne pathogens, thereby ensuring better health outcomes.

NARMS would be even more useful if it were combined with comprehensive, government-collected data on drug use in farm animals to better understand pressures leading to change in resistance.

Second, it is essential for the FDA Science Board Advisory Committee to take this opportunity to state that USDA NARMS data should be adequate and should be considered in public health surveillance and goal setting.

The Department of Health and Human Services is currently in the final stages of a midterm review of the Healthy People 2010 Initiative. Keep Antibiotics Working and other public health advocates strongly objected to the proposed deletion from Healthy People 2010 of targets relating to resistance in *Salmonella* slaughter isolates from cattle, swine, and chickens. Unfortunately, we believe this deletion will be accepted. The USDA argued that this aspect of Healthy People 2010 should be deleted due to lack of data pertaining to *Salmonella* species isolated from animals at slaughter. Yet, the FDA Center for Veterinary Medicine's website clearly states that the USDA is collecting this data as part of its NARMS work.

Animal isolates were included in NARMS because of the potential for antimicrobial drug use in animals to select for resistance and because foods of animal origin are the most likely source of resistant foodborne pathogens, particularly in the case of *Salmonella*. *Salmonella* is the second most common bacterial foodborne pathogen in the United States, resulting in illness to over a million people each year. The goal of the veterinary arm of NARMS is to "is to track the development of antimicrobial resistance in veterinary isolates as it arises and disseminate the information to all stakeholders in an attempt to arrest the development and spread of resistance, especially among foodborne pathogens." We believe deletion of this aspect of Healthy People 2010 is a serious setback for public health.

The USDA's position seems to be that although the agency is using public funds to conduct surveillance, the agency does not want this data to be used as the basis for taking action to address the problem being monitored. This is unacceptable. NARMS was created to monitor resistance to protect human and animal health. NARMS animal data must be adequate to be used for setting public health objectives. If it is not, the FDA Science Board Advisory Committee should ask how surveillance and data collection can be improved to fulfill the stated mission to track resistance in a manner that provides the public health benefit of detecting problems with resistance when they arise.

I request that the FDA Science Board Advisory Committee issue a public statement that the data the USDA collects is not valuable in itself unless it has public health implications and that USDA must operate a program that is good enough for goal setting. If the USDA does not intend its surveillance program to be used for goal setting then public funds should not be used for collecting this data.

Third, transparency and the opportunity for public review and participation are important in everything that the FDA does related to public health, including the Science Board's review of NARMS.

I commend you for including an open public hearing as part of today's program.

I would like to take this opportunity to request that full transcripts from the FDA's review of NARMS be made public.

Thank you very much for this opportunity to comment today on the NARMS review process. I look forward to hearing from you on the availability of the transcripts from the FDA's NARMS review.

Susan Prolman, Esq.
Washington Representative
Food and Environment Program
Union of Concerned Scientists
202-331-5433
sprolman@ucsusa.org
1707 H Street, NW Suite 600
Washington, DC 20006